Background

The implementation of Policy 1406 on The Ethics of Research Involving Human Subjects has exposed some challenges regarding the review of research protocols submitted by “practitioner-researchers.” “Practitioner-researchers” are those individuals—typically in professional faculties and disciplines such as Education, Nursing, Medicine, Clinical Psychology, and Social Work—who conduct research on or with individuals (some of whom may be minors) who are receiving care or instruction from the investigator in his/her capacity as a service provider or educator. Because the practitioner-researcher is playing a dual role, there is the potential that certain ethical principles may be compromised, and accordingly, the practitioner-researcher must be acutely sensitive to questions about the voluntariness of participation, the vulnerability of participants, the potential for a conflict of interest on the part of the researcher, and whether consent is fully informed.

The purpose of this document is to provide some guidelines to researchers on the preparation of research protocols for ethics review. These guidelines identify areas of concern in the evaluation of protocols that employ participatory, action or “practitioner-research” approaches.

Defining Terms

Before outlining a set of guidelines for researchers, it is important to clarify the language used in this document. This document refers to “practitioner-research” in a generic sense. Practitioner-research is conducted by an individual who assumes a dual role—both as a practitioner or provider of services (clinical, nursing, or instructional, for example) and as a scientific researcher. MacLeod defines practitioner research as “research carried out by practitioners for the purpose of advancing their own practice.”

In some disciplines, notably education, this kind of research is typically referred to as “participatory research” or “action research” conducted by a “reflective practitioner.” In other disciplines, and more generally in qualitative research and some forms of evaluation research, participatory action research (PAR) has a different meaning. One definition of PAR is as follows:

Participatory Action Research provides a reflective and disciplined approach to

university research and outreach programming that places the study site and its constituents at the heart of the research process. Participatory action research not only incorporates the collective knowledge of the community, it gives the community ownership of the research and its results, and increases the likelihood that results will be actively applied. Dubbed "PAR" by a growing global cohort of practitioners, Participatory Action Research is associated with traditions of theory and practice in a wide range of fields. Participatory Action Research recognizes that practitioners, community members, citizens, employees, and volunteers can generate critical knowledge about social, political, economic, technical, cultural, and organizational problems.²

The salient issue, from the perspective of ethics review, centres less on the methods employed, and more on the articulation of the role of the researcher, the role of the participants, and the relationships between the researcher and participants as this relates to ethical principles in the conduct of research.

Guidelines for Researchers

In accordance with established procedures, individuals conducting research involving human subjects must complete the Protocol Submission Form (available at http://www.umanitoba.ca/research/ors/ethics/human/). The Protocol Submission Form requires the researcher to address questions regarding issues such as informed consent, voluntary participation and coercion, and the relationship between the researcher and the researched.

Article 2.1 of the Tri-Council Policy Statement (TCPS) states that

Research governed by this Policy (see Article 1.1) may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research.

Article 2.2 of the TCPS states that

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

The element of voluntariness has important implications. Consent must be freely given and may be withdrawn at any time. Undue influence may take the form of inducement, deprivation or the exercise of control, or authority over prospective subjects.

Voluntariness is especially relevant in research involving restricted or dependent

subjects, and is absent if consent is secured by the order of authorities or as a result of coercion or manipulation. The influence of power relationships on voluntary choice should be judged according to the particular context of prospective subjects. For example, the voluntariness of prisoners, members of organizations with authoritarian structures (such as the military, police, some religious groups or street gangs), or of employees or students may be restricted because their institutional context implies undue pressure. Care should be exercised in developing relationships between researchers and authorities, so as not to compromise either the free and informed consent or the privacy and confidentiality of subjects...

REBs should also pay particular attention to the elements of trust and dependency, for example, within doctor/patient or professor/student relationships, as these can constitute undue influence on the patient to participate in research projects, especially those involving residents in long-term care facilities or psychiatric institutions.

Researchers should avoid being put in a position of becoming informants for authorities or leaders of organizations. The offer of benefits in some contexts may amount to undue inducement, and thus negate the voluntary aspect of the consent of subjects who may perceive such offers as a way to gain favour or improve their situation.

In “practitioner research,” the issues of informed consent and the voluntariness of participation are of paramount concern to the researcher as well as those who are the subjects in the research. It is incumbent upon the researcher to consider his/her role in the research, and to demonstrate how the possibility of participant coercion will be obviated.

In the design of the research, and in the preparation of the research protocol for ethics review, the practitioner researcher should ask the following kinds of questions:

- How will you, as a researcher, assure subjects, clients, or parents/guardians that subjects are truly free to participate, or to absent themselves from participation?
- By what means will subjects be assured that their participation is entirely voluntary?
- How will the researcher assure subjects, clients, or parents/guardians that subjects who refuse to participate or who do not receive a parent’s or guardian’s permission to participate will not be penalized in any way?

Researchers may be able to address some of these concerns through the information provided.

In terms of the power relationship that exists between service provider and client:

- In general, someone other than the researcher should approach subjects in the first instance and explain that non-participation is a clear option and that no
penalty whatsoever would be attached to non-participation. This person should not be a person in a perceived position of power vis-a-vis the client (not another teacher, the principal, or the doctor, for example).

- It should be clear that subjects may choose not to be involved in any aspect of the study (at least in terms of data collection), such as not answering questions or being involved in some activities.

- The procedures used in the study should fall within the generally accepted framework expected by the profession (activities that fall under the provincial curriculum, for example). The boundaries of the procedures need to be made clear in the letters of consent and subjects (or their guardians, etc) should be made aware of how this fits into the accepted framework.

- Subjects should not be advantaged in any way as a result of taking part in the research study, since this constitutes a penalty for non-involvement. For example, they should not receive special attention or additional help from the researcher.

- In general, if documents which are part of the day-to-day activities of the provider/client relationship (e.g., class assignments, school records, patient charts) are used as assessment instruments (for assigning grades, for example), the practitioner-researcher should be unaware of who has and who has not agreed to participate in the study until the end of the provider-client relationship. For example, a teacher should not be aware of who the subjects in the study are until grades have been assigned at the end of term. Some system should be set in place (having the subjects’ work photocopied until after term by someone who will not reveal the names of the subjects) to protect the possible bias in providing care based on participation in the study.

- Every effort should be made to inform subjects fully about the study; deception should only be used if no other method can be found.

In short, researchers must consider the advantages and disadvantages of using a population with whom they have a prior (and on-going) relationship, and especially where that relationship involves an unequal relationship.\(^4\)

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\(^4\)Similar issues arise when researchers are engaged in research in their own workplace. While conducting research in this type of setting may be convenient and highly expedient (primarily in terms of gaining access to a readily available pool of research participants), the researcher must be mindful that participants may feel an element of coercion in their participation in the research, particularly if the researcher is in a supervisory or even a more senior position to them. Researchers should be aware that conducting research in the workplace may inhibit participants in terms of the frankness of their responses, and it may very well affect the relationship between the researcher and his/her co-workers or staff.